Technology Assessment Program
Office of Patient Care Services

Bibliography*: Robotic surgery - Update 2006

*Selected, quality filtered, not subject to external review

Background: The VA Chief Patient Care Services Officer (CPCSO) requested guidance on a decision to purchase robotic surgery devices for use in VA. This request is the first handled by VA's new Technology Assessment Advisory Group (TAAG) within the Office of Patient Care Services (OPCS), which was created to deliver evidence-based recommendations for use of new technologies in VA in a timely manner. As part of this new process, the VA Technology Assessment Program (VATAP) is charged with providing the best available evidence on a topic within a two-week time period.

This report will update VATAP's previous bibliography report on robotic surgery produced in 2004 (VATAP 2004). As before, it will consider only robotic surgical devices that have received FDA approval. It will also consider all available indications for use of robotic-assisted surgery compared with existing surgical procedures.

Methods: In September 2006, VATAP conducted multiple searches to update its previous report on robotic surgery. First, VATAP queried the FDA databases for new approvals by device developers, along with searches of the Dialog databases covering the FDA and device industries (PROMT, Health Devices Alerts, DIOGENES, FDA News, ESPICOM). The FDA-focused searches yielded no additional new product approvals.

VATAP then searched the Cochrane Library for assessments and reviews published since 2003. Finally, VATAP ran searches on the Dialog databases (MEDLINE, EMBASE, Current Contents, Science Citation Index, and BIOSIS) using variations of the descriptors and concepts for robotic surgery in humans. All languages and all adult ages (excluding infants, children and adolescents) were considered and evidence filtered for the years 2002 through September 2006.

VATAP included only studies that met the following criteria:

- Studies reporting primary data and outcomes using FDA-approved robotic surgery technology;
- Published with abstract or full text in English;
- N ≥ 12 consecutive live, human subjects;
- High quality evidence reviews or health technology assessments[1] (HTA);
- The most recent or largest version of a study by the same investigators for the same purpose (to eliminate redundancy).

Meeting abstracts, studies of only visual-assisted devices, studies of cadavers and studies already reviewed in published HTAs or evidence reviews were excluded.

[1]Health Technology Assessment (HTA) is a multidisciplinary field of policy analysis that systematically studies the medical, social, ethical, and economic implications of development, diffusion, and use of health technology.

Results: VATAP searches identified 108 citations on robotic surgery published since 2002. TAP retrieved 42 articles that were thought to be relevant to robotic surgery based on a review of title and abstract information. Twenty-six articles met criteria for inclusion in the report, including four HTAs (Tooher 2004; Tooher 2005; ASERNIP-S 2004; NICE 2004) and 22 primary studies. Four of the primary studies (Morino 2004; Morgan 2005; Bhayani 2005; Nakadi 2006) provided some degree of cost analysis. In addition, one national guidance document from the National Institute for Clinical Excellence in the United Kingdom (NICE 2005) was identified and included in Table 3.

Table 2 provides a concise overview of the surgical applications studied and corresponding levels of evidence included in this update. Table 3 provides citation detail for all included reviews and primary studies, along with the NICE guidance. Excluded studies are listed in the end references.

The Australian Safety and Efficacy Register of New Interventional Procedures—Surgical (ASERNIP-S), which conducts systematic reviews of new and emerging surgical techniques and technologies under the auspices of the Royal Australasian College of Surgeons, produced two relevant and comprehensive reviews of robotic surgery that provide the basis for this update (Tooher 2004; Tooher 2005). These reviews focused on the daVinci system (Intuitive Surgical, Inc.; Sunnyvale, CA), the robotic surgery technology for which there was the most evidence available.

In order to meet the two-week time frame for the TAAG process, no in-depth critical quality appraisal of included primary studies was attempted, but a level of evidence was assigned using the Hierarchy of Evidence framework developed by the National Health and Medical Research Council of Australia (NHMRC 2000) (See Table 1). This framework was chosen because it was applied in both ASERNIP-S reports (Tooher 2004; Tooher 2005), appears to be a reasonable framework to apply to studies of surgical interventions, and offers consistency with which to gauge the progression of the evidence base published since the ASERNIP-S reviews.

Table 1. NHMRC (2000) Hierarchy of Evidence

Level of evidence	Study design
I	Evidence obtained from a systematic review of all relevant randomized controlled trials
II	Evidence obtained from at least one properly-designed randomized controlled trial
III-1	Evidence obtained from well-designed pseudo-randomized controlled trials (alternate allocation or some other method)
III-2	Evidence obtained from comparative studies (including systematic reviews of such studies) with concurrent controls and allocation not randomized, cohort studies, case-control studies, or interrupted time series with a control group
III-3	Evidence obtained from comparative studies with historical control, two or more single arm studies, or interrupted time series without a parallel control group
IV	Evidence obtained from case series, either post-test or pre-test/post-test

Thirteen indications for using robotic-assisted endoscopic procedures were identified, of which radical prostatectomy was the procedure for which there was the most evidence (in terms of numbers of independent studies), followed by cholecystectomy and mitral valve repair. The highest levels of evidence (shaded cells in Table 2) were randomized clinical trials (Level II) of

the Nissen fundoplication procedure, bearing in mind that three Level III-1 trials in adrenalectomy, cholecystectomy and gastric bypass may, in fact, be Level II except for the incomplete reporting of the randomization procedure. In addition, while adrenalectomy, pyeloplasty, mitral valve repair, and gastric bypass procedures showed a slight improvement in the level of available evidence since the publication of the ASERNIP-S reviews, the overall evidence base for these applications is still very sparse.

Table 3 shows that the vast majority of evidence assessed the performance of the daVinci system for a range of indications, followed by the ZEUS-AESOP system used in laparoscopic cholecystectomy procedures.

Table 2. Overview of Indications and Corresponding Levels of Evidence Meeting Inclusion Criteria

Note: shaded cells represent highest levels of evidence to date

		Level of evidence (# studies)					
Indication for use	**# reviews**	**I**	**II**	**III-1**	**III-2**	**III-3**	**IV**
Adrenalectomy				1*			
Radical prostatectomy	1 (Level III-2 & III-3 studies)				1	1	2
Pyeloplasty					2		1
Left ventricular epicardial lead implantation	1 (Level IV studies)						
Coronary artery bypass	1 (Level IV studies)						
Mitral valve repair					1		2
Thymectomy							1
Cholecystectomy (includes one study w/ hernioplasty)				2*	2		1
Nissen fundoplication			2				
Gastric bypass				1*			
Partial nephrectomy							1
Sacrocolpopexy							1

* indicates randomization procedure not defined, could be a Level II study.

Conclusions/Discussion: To evaluate the progression of the evidence base, VATAP compared the levels of new evidence with the highest levels of evidence reviewed in both ASERNIP-S reports (Tooher 2004; Tooher 2005). Tooher (2004) concluded that for a range of robotically-assisted endoscopic procedures: "…there is insufficient evidence to make many useful comparisons of robotic-assisted and conventional laparoscopic surgery, particularly in regard to the cost-effectiveness of robotic-assisted surgery." The evidence for robotically-

assisted laparoscopic radical prostatectomy suggested improvement in functional recovery time and a shortened operative time, but the safety and efficacy of the procedure depended on expertise, long-term cancer control and survival using laparoscopic procedures was unknown, and investment in robotics came with high up front costs and maintenance costs (Tooher 2005). They concluded no clear advantage of robotically-assisted techniques versus either standard laparoscopic procedures or open procedures. Furthermore, the limitations on clinical use that were noted in the previous VATAP bibliography (2004) still persist: high initial investment and operating costs; substantial training requirements; and lack of strong evidence from well-designed clinical trials from which to determine effectiveness and cost-effectiveness relative to current practices. The additional evidence found in this update, even from the small randomized clinical trials, would not alter these conclusions.

Recent HTAs call for controlled diffusion of surgical robotics with monitoring and audit to ensure patient safety. Concentrating the use of this technology in specialized surgical centers with access to conventional surgical techniques would facilitate training and assist clinical research in defining appropriate indications for use and patient selection criteria and in comparing clinical risks and benefits of robotic surgery to current surgical practices. Finally, monitoring the literature would be important for identifying new evidence of effectiveness and cost-effectiveness as it becomes available.

Recommendations to the TAAG: While the evidence does not confer clear advantages to using robotically-assisted surgical procedures, there may be other compelling reasons to further evaluate certain applications for use in VA, for example, the prevalence of disease or condition or the ability to address staffing shortages in the surgical theater in a safe and cost-effective manner. With that in mind, the robotically-assisted laparoscopic applications with the best available evidence for prevalent health conditions in VA that may offer safe and cost-effective alternatives to current practices are:

1. Radical prostatectomy—although the evidence base consists of non-experimental studies, this application has been the most widely studied to date. There is significant media and professional interest in this procedure.

2. Nissen fundoplication—the evidence from two independent, experimental studies shows comparable feasibility and safety of robotically-assisted Nissen fundoplication to the standard procedure, but the investigators tempered their conclusions due to the high costs and longer operating times.

3. Cholecystectomy—the evidence from two independent, experimental studies suggests comparable feasibility and efficacy of the robotically-assisted procedure using the Zeus/AESOP system to the standard procedure. The robotically-assisted procedure has some technical advantages but also takes longer. Using the Zeus/AESOP system would require additional investment and training, since the other procedures use the daVinci system.

Table 3. Evidence on Robotics Surgery Published Since 2003

Citation	Application	Device	Level of evidence
ASERNIP-S (Tooher 2004)	Various: Urological Cardiac Thoracic General surgery Gynecological Pediatric	DaVinci	Comprehensive review provides evidence base through April 2004 (of Level III-2, III-3, and IV studies)
Urological			
Morino 2004	Robot-assisted vs. laparoscopic adrenalectomy	DaVinci	RCT (Level II/III-1) Cost study N=20
ASERNIP-S (Tooher 2005)	Comparison of laparoscopic radical prostatectomy (LRP) procedures	DaVinci	Systematic review (of Level III-2 and III-3 studies)
Mikhail 2005	RAP in overweight vs. obese patients vs. normal weight controls	DaVinci	Comparative study case series with concurrent control (Level III-2) N=150
Kaul 2005	Veil nerve sparing Robot-assisted LRP (RAP)	DaVinci	Case series (Level IV) N=154
Hu 2006	LRP vs. RAP	DaVinci	Comparative study with historical control (level III-3) N=1,188
Atug 2006	Impact of learning curve on surgical margins positivity in RAP	DaVinci	Case series (Level IV) N=140
Palese 2005	Robot-assisted laparoscopic dismembered pyeloplasty	DaVinci	Case series (Level IV) N=35
Bhayani 2005	Robot-assisted vs. standard laparoscopic pyeloplasty	DaVinci	Comparative study case series with concurrent control (Level III-2) Cost study N=21
Link 2006	Robotic laparoscopic pyeloplasty vs. transperitoneal lap pyeloplasty	DaVinci AESOP	Comparative study with concurrent controls, not randomized (Level III-2) N=20
Cardiac			
ASERNIP-S April 2004	Robotically assisted left ventricular epicardial lead implantation vs. open surgical procedure	DaVinci	Horizon scanning summary-evidence of safety and efficacy consists of 5 case series and 2 case reports (Level IV)
NICE November 2004	Totally endoscopic robotically assisted coronary artery bypass surgery	DaVinci Zeus	Brief overview—evidence base consists of 4 case series with carefully selected cohorts from German centers (Level IV)
NICE June 2005	Totally endoscopic robotically assisted coronary artery bypass surgery	All	Interventional Procedure Guidance: Current evidence of safety and efficacy does not appear adequate for this procedure to be used without special arrangements for consent and for audit or research.
Morgan 2005	Mitral valve repair Atrial septal defect closure	DaVinci	Retrospective case series (Level IV) Cost study N=40

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Citation	Application	Device	Level of evidence
Nifong 2005	Robot-assisted mitral valve reconstruction	DaVinci	Prospective, FDA-approved Phase II multicenter case series (Level IV) N=112
Woo 2006	Minimally invasive robot-assisted vs. sternotomy mitral valve reconstruction	DaVinci	Comparative study with concurrent controls, not randomized (Level III-2) N=64
Thoracic			
Rea 2006	Thymectomy	DaVinci	Case series (Level IV) N=33
General surgery			
Nio 2004	Robot-assisted vs. conventional lap cholecystecomy	Zeus-AESOP	Comparative study with concurrent controls and allocation not randomized (Level III-2)
Kraft 2004	Robotic vs. human assisted Lap cholecystectomy+ hernioplasty	AESOP	Comparative study with concurrent controls and allocation randomized (Level II/III-1) N=240
Caratozzolo 2005	Robot-assisted lap cholecystectomy	ZEUS-AESOP	Case series (Level IV) N=29
Kornprat 2006	Robot-assisted vs. standard lap cholecystectomy	ZEUS-AESOP	Comparative study with concurrent controls and allocation not randomized (Level III-1) N=46
Zhou 2006	Robot-assisted vs. standard lap cholecystectomy	ZEUS-AESOP	Comparative study with concurrent controls and allocation randomized (Level II/III-1) N=40
Morino 2006	Robot-assisted lap vs. standard lap Nissen fundoplication	DaVinci	Prospective randomized controlled trial (Level II) N=50
Nakadi 2006	Robot-assisted lap vs. standard lap Nissen fundoplication	DaVinci	Prospective randomized controlled trial (Level II) Cost study N=20
Sanchez 2005	Laparoscopic Roux-en-Y gastric bypass (LRYGB) vs. totally robotic LRYGB	DaVinci	Prospective randomized controlled trial (Level II/III-1) N=50
Gettman 2004	Robot-assisted laparoscopic partial nephrectomy	DaVinci	Case series (Level IV) N=13
Gynecological			
Elliott 2004	Robotically assisted laparoscopic sacrocolpopexy	DaVinci	Case series (Level IV) N=20

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VA Technology Assessment Program
Office of Patient Care Services (11T)
VA Boston Healthcare System
150 South Huntington Avenue
Boston, MA 02130

Tel: 617.278.4469 Fax: 617.264.6587
vatap@med.va.gov
http://www.va.gov/vatap http://vaww.va.gov/vatap

Author: Elizabeth Adams, RRT, MPH
Research Analyst, VA Technology Assessment Program

Contributors: Elaine Alligood, MLS
Information Specialist, VA Technology Assessment Program

Valerie Lawrence, MD
Physician Advisor, VA Technology Assessment Program

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